HFI-35 6/25/99 WRG

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-71

June 23, 1999

Eduardo Lucero, President
E.D.E. International, Inc.
D/B/A Full Moon Seafood
1204 N.W. 72nd Avenue
Miami, Florida 33126
CFN: 1063997

Dear Mr. Lucero:

On January 25 and 26, 1999, the Food and Drug Administration (FDA) conducted an inspection of your fish importing facility, located at 1204 N.W. 72nd Avenue, Miami Lakes, FL 33126. Investigator Maria A. Medina documented serious deviations from the seafood importing regulations found at Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). The existence of these deviations cause the fish products being imported and distributed by your firm to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The following deficiencies were noted:

> Failure to establish product specifications that are designed to ensure that the seafood products are not adulterated, as required in 21 CFR § 123.12(a)(2)(i).
>
> Failure to adequately perform one or more of the affirmative steps required in 21 CFR § 123.12(a)(2)(ii) to verify that the seafood products are processed in accordance with the provisions of the HACCP regulations.

In addition, your firm has failed to have and implement written verification procedures that ensure that the seafood products were handled in accordance with the requirements of 21 CFR § 123.12(a)(2).

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt action to correct these and all violations at your firm. Failure to achieve correction may result in regulatory action without further notice. These actions may include seizure, injunction, or removal from the European Union (EU) list. Additionally, until FDA is satisfied that the above deficiencies have been corrected, no EU certificates will be issued. In addition, FDA may detain your imported seafood products without examination until compliance with the seafood regulations is achieved and verified.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct this violation, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Carlos I. Medina, Compliance Officer, Food and Drug Administration, 6601 Northwest 25th Street (P.O. Box 59-2256), Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen
Director, Florida District